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Food Safety  
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## AUDIT REPORT FOR FINLAND

August 15 through 30, 2001

### INTRODUCTION

#### Background

This report reflects information that was obtained during an audit of Finland's meat inspection system from August 15 through 30, 2001. The seven establishments certified by Finland as eligible to export meat to the United States were audited. Six of these were slaughter and processing establishments; the other one was a cold storage facility.

The last audit of the Finnish meat inspection system was conducted in September-October 2000. The same seven establishments were audited: all were evaluated as acceptable. At that time, the following major concerns were identified:

1. In-plant inspection staff lacked HACCP-Pathogen Reduction training.
2. Dropped meat reconditioning procedures were inadequate.
3. In four of the six slaughter establishments, condemned materials were not denatured.
4. In five of the six slaughter establishments, statistical control procedures had not been developed to evaluate *E. coli* testing results.
5. No field samples were being analyzed for arsenic or mercury.

At the time of this audit, only pork products were eligible for export to the United States from Finland.

From January 1 through June 30, 2000, Finnish establishments exported 1,183,555 lbs. of pork products to the U.S. The only port-of-entry rejection during this period was for transportation damage, and consisted of only 33 lbs. of product.

### PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Finnish national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in the meat inspection headquarters facilities preceding the on-site visits. The third was conducted by on-site visits to establishments and to one pig farm. The fourth was a visit to two laboratories, one performing analytical testing of field samples for the national residue testing program, and the other culturing field samples for the presence of microbiological contamination with *Salmonella* species and generic *Escherichia coli* (*E. coli*).

Finland's program effectiveness was assessed by evaluating five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/

processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials (this was the case with two establishments—see below).

## RESULTS AND DISCUSSION

### Summary

Effective inspection system controls were found to be in place in five of the seven establishments audited; four of these (Ests. 10, 18, 22, and 6472) were evaluated as acceptable and one (Est. 62) was recommended for re-review. Two establishments (74 and 78) were found to be unacceptable. Details of audit findings, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* and generic *E. coli*, are discussed later in this report.

As stated above, five areas of major concern had been identified during the last audit of the Finnish meat inspection system, conducted in September-October 2000. The Auditor determined that most of these had been adequately addressed and corrected, as indicated below:

- ◆ In-plant inspection staff had lacked HACCP-Pathogen Reduction training. *During this new audit, the auditor determined that some improvement had been made, but that, in the majority of the field inspection personnel, the knowledge of the requirements for compliance with HACCP programs remained inadequate.*
- ◆ Dropped meat reconditioning procedures had been inadequate. *This had been corrected.*
- ◆ In four of the six slaughter establishments, condemned materials had not been denatured or decharacterized. *Significant improvement was seen in most establishments; condemned materials that should have been denatured in Est. 62 were not.*
- ◆ In five of the six slaughter establishments, statistical control procedures had not been developed to evaluate *E. coli* testing results. *This had not been corrected; however, by the time the new audit of Finland was completed, the development of the necessary procedures was already well underway.*

- ◆ No field samples were being analyzed for arsenic. *This had been corrected.*

In addition to the above, the following major concerns were also identified during this new audit:

1. Personal hygiene deficiencies resulted in product contamination in three establishments.
2. Insanitary dressing procedures were found in two establishments.
3. In three establishments, equipment was not sterilized as required.
4. Exposed product found was stored below condensation problem areas in three establishments.
5. Lighting at post-mortem inspection surfaces was inadequate in four of the six slaughter establishments.
6. Inadequate pre-boning trim was observed in two establishments.
7. Common contact was found in three establishments.
8. Maintenance of over-product structures and equipment was inadequate in three establishments.
9. No species verification was being performed in any of the establishments.
10. Finland had informed FSIS that European ISO methodologies were being used for the culturing of field samples for generic *E. coli* and *Salmonella* species. This policy had been changed, and different methods were now in use; these had not been submitted to FSIS as required for equivalence determination.
11. Internal reviews (required monthly) had not been conducted monthly in three establishments.

#### Entrance Meeting

On August 15, an entrance meeting was held in the Helsinki offices of the National Food Agency (NFA), and was attended by Drs. Jorma Hirn, Director General; Osmo Mäki-Petäys, Director, Meat and Fish Hygiene Unit; Anna-Maija Grönlund, Anne Fagerlund, and Eero Lääkkö Senior Officers; and Dr. Gary D. Bolstad, International Audit Staff Officer, Field Operations, Food Safety and Inspection Service, U.S. Department of Agriculture, hereinafter referred to as *the Auditor*. Topics of discussion included the following:

1. The Auditor provided import and port-of-entry rejection data for Finnish products received for the current year through June 30.
2. The Auditor provided the Finnish officials with copies of the data-collection instruments he would be using for gathering information on Finland's compliance with the requirements for HACCP programs, SSOPs, and generic *E. coli* and *Salmonella* testing programs.
3. The Auditor advised the Finnish officials that there would be a major emphasis on enforcement controls during the fiscal year 2002 audits of importing countries.

### Headquarters Audit

The Finnish officials informed the Auditor that the meat inspection organization had undergone a reorganization: the previous National Veterinary and Food Research Institute (EELA) was now the National Food Agency (NFA). A summary of the new organizational structure was provided.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The FSIS auditor observed and evaluated the process.

The Auditor conducted a review of inspection system documents pertaining to the establishments listed for records review. This records review, conducted at the NFA headquarters in Helsinki, focused primarily on food safety hazards and included the following:

- Training records for inspectors, especially regarding PR-HACCP were provided. The Finnish officials stated that the field personnel had received training and instruction.
- Consumer complaints and product recall actions
- Animal disease status
- Records of supervisory visits to U.S. certified establishments
- Labeling records
- New laws/regulations/directives/ guidelines
- Official communications with field personnel, both in-plant and supervisory, in which U.S. requirements are conveyed
- Examples of official communication from the field regarding reports of questionable or faulty compliance with U.S. requirements were requested; the Finnish officials stated that these were usually communicated by telephone.

No concerns arose as a result the examination of these documents.

## Government Oversight

All inspection veterinarians and inspectors in establishments certified by Finland as eligible to export meat products to the United States were full-time NFA employees, receiving no remuneration from either industry or establishment personnel.

## Establishment Audits

Seven establishments were certified to export meat products to the United States at the time this audit was conducted; all were visited for on-site audits. In five of these, except as otherwise noted in the body of this report, both NFA inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products.

## Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information was also collected about the risk areas of government oversight of private laboratories, intra-laboratory quality assurance procedures, including sample handling, and methodology.

The National Veterinary and Food Institute Laboratory in Helsinki was audited on August 17, 2001. Effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions. The methods used for the analyses were acceptable. No compositing of samples was done (this was not a deficiency).

No organophosphates had been detected in field samples for the previous ten years, and Finland was phasing out sampling for organophosphates as part of the national residue-testing program. Seventeen field samples were analyzed for organophosphates in 2000 and five in 2001.

- ◆ One area of concern was identified: positive organophosphate-spiked samples were run with each sample set, but no unknown or blank intralaboratory check samples were being provided to analysts.

Finland's microbiological testing for *Salmonella* was being performed in private laboratories. One of these, in Establishment 78 in Kauhajoki, was audited. The auditor determined that the system met the criteria established for the use of private laboratories under FSIS's Pathogen Reduction/HACCP rule. These criteria are:

1. The laboratories have been accredited/approved by the government, accredited by third party accrediting organization with oversight by the government, or a government contract laboratory.
2. The laboratories have properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record-keeping capabilities.
3. Results of analyses are being reported to the government or simultaneously to the government and establishment.

The details of the findings in this microbiology laboratory are discussed later in this report.

#### Establishment Operations by Establishment Number

The following operations were being conducted in the seven establishments:

Swine and beef slaughter, cutting, and boning; ham, pork and beef (cooked) sausages, and slicing of dry salami (produced in other establishments); and ground beef production – one establishment (62)

Beef, swine, and lamb slaughter, cutting, and boning; dry sausage production – Est. 10

Swine slaughter, cutting, boning, and curing (hams) – Est. 18

Beef and lamb slaughter; beef cutting and boning – Est. 74

Swine slaughter, cutting, and boning – Est. 22

Beef slaughter, cutting, boning – Est. 78

Cold storage – Est. 6472

#### SANITATION CONTROLS

Based on the on-site audits of establishments, Finland's inspection system had controls in place for water potability, back-siphonage protection, operation and inspectors' work space, ventilation, ante-mortem facilities, outside premises, product and reconditioning and transportation, pre-operational and operational sanitation, and waste disposal.

#### Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A). The following deficiencies with the SSOPs were found:

- ◆ Documentation of operational sanitation activities was inadequate in three of the seven establishments (18, 74, and 78). This was a repeat finding in Est. 78.

- ◆ In Est. 78, there was no documentation of condensation control (condensation was one of the major findings during the audit).
- ◆ In Est. 74, there was no concise description of the sanitation program, and the only daily documentation of operational sanitation activities was the monitoring of sterilizer temperatures. Also, some documentation of pre-operational sanitation was available, but it was in need of improvement.

Furthermore, the following sanitation problems were identified:

#### Product Contamination

- ◆ Insanitary dressing was observed in Establishments 74 and 78. Corrective actions were ineffective.
- ◆ In half of the six slaughter establishments, personal hygiene deficiencies resulted in product contamination. In Est. 74, corrective actions were inadequate. In Est. 78, maintenance personnel were observed to fail to observe elementary principles of basic hygiene during their attempts to deal with structural and maintenance deficiencies identified during the audit. They were observed to handle product-contact equipment that was in place and ready for use to receive exposed product and to work with their tools on structures directly above exposed-product contact surfaces. Corrective actions were not immediate. In Ests. 62, and 10, NFA ordered immediate and appropriate corrective actions.
- ◆ Failure to sterilize equipment as required was observed in three establishments. In Ests. 74 and 78, consecutive carcasses were routinely contacting adjacent equipment. This specific problem had been identified during previous FSIS audits of these establishments, and no corrective actions had been taken in spite of assurances that they would be. In Est. 62, the splitting saw was not sterilized between carcasses. This had been identified by the Veterinarian-In-Charge; she ordered installation of sterilizing equipment.

#### Product Handling and Storage

- ◆ Exposed product was observed directly below condensation in three establishments. In Est. 78, corrective actions were not consistently effective. In Est. 10, corrective actions were effective for the majority of the exposed product; new carcasses were positioned under one of the problem areas, but no product was seen to be affected before effective corrective actions were taken. In Est. 62, the affected product was immediately identified for reinspection and trimming and the area was rejected for use by the establishment pending correction.

## Facilities and Equipment

- ◆ An intensity of 540-Lux (fifty foot-candles) of light is required, by EC Directive, on carcass surfaces requiring inspection. Light at inspection surfaces was found to be inadequate in Est.18 (in abdominal cavities), Est.22 (viscera trays), Est. 62 (mandibular lymph nodes), and exceptionally so in Est. 74 in abdominal cavities, on some of the surfaces of the liver, and (only 55 Lux, or 5 foot-candles) on the incised masseter muscles. NFA ordered prompt corrections.
- ◆ Inadequate maintenance of structures and equipment was observed in Ests. 10, 18, and especially in Est. 78. Improvements were programmed.
- ◆ In Est. 22, the door to a toilet entered directly into a production area. The management representative rejected the room for use.
- ◆ In Est. 78, there were no facilities for hand washing at the pre-boning trim station. Corrective actions were neither immediate nor effective.
- ◆ In Est. 78, straps on mesh aprons were found to have thick buildups of old product residues caked onto the fabric. The establishment management representative ordered them to be cleaned before being used again.
- ◆ The entire ceiling in the carton storage area in Est. 78 consisted of unclad, fibrous insulation material. The management representative said it would be corrected.

## Personal Hygiene

- ◆ In Est. 78, lockers were observed in both male and female welfare areas into which workers had placed work clothes, rather than into the laundry for cleaning. The management representative said the employees would be notified.
- ◆ Maintenance personnel in Est. 78 were observed to fail to observe elementary principles of basic hygiene during their attempts to deal with structural and maintenance deficiencies identified during the audit. They were observed to handle product-contact equipment that was in place and ready for use to receive exposed product and to work with their tools on structures directly above exposed-product contact surfaces. Corrective actions were ineffective.

## ANIMAL DISEASE CONTROLS

Finland's inspection system had controls in place to ensure adequate animal identification, ante-mortem inspection procedures and dispositions, restricted product control, and procedures for sanitary handling of returned and rework product.

Finland had implemented controls for the detection of any cases of Bovine Spongiform Encephalopathy: a plan was underway to examine 25-30,000 animals (all sick animals over 24 months, all imported animals at slaughter, and the rest healthy animals over 30 months at slaughter) in CY 2001. No BSE had, as of the time of this audit, been diagnosed in Finland.

The following deficiencies were identified:

- ◆ The post-mortem inspector in Est. 74 failed to observe the cut surfaces of incised mandibular lymph nodes. The Veterinarian-In-Charge corrected this immediately.
- ◆ Condemned carcasses were not denatured in Est. 62. The auditor explained the requirement; inspection officials stated that they understood.

There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit.

## RESIDUE CONTROLS

Finland's National Residue Testing Plan for 2000 was being followed, and was on schedule. The Finnish inspection system had adequate controls in place to ensure compliance with sample handling and frequency, timely analysis, data reporting, tissue matrices, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, corrective actions, sampling and reporting procedures, and storage and use of chemicals. Methodologies were acceptable, and prior deficiencies had been corrected.

- ◆ There was one area of concern: positive spiked samples were run with each organophosphate sample set, but no unknown or blank intra-laboratory check samples were provided to analysts.

## Farm Visit

The Auditor paid a visit to a farm in Pernaja, Southern Finland, where swine were raised for supply to one of the establishments eligible to export to the United States, on August 21. The property housed 100 sows and 500 fattening pigs. The feed used was mostly homegrown wheat, and oats, mixed with commercial pelletized food, and some cheese. The only added supplements were Vitamin E and selenium.

There was no routine treatment for ectoparasites in Finland in general. The only routine treatment with veterinary drugs was for endoparasites (roundworms) with Nemavet, the active ingredient of which is Fenbendazole; this medication was given twice yearly to the sows and to the piglets once at 7 weeks of age. The withdrawal period for this product is 21 days. There was adequate documentation of medication given to the pigs on the farm. In

addition to documentation recorded by the date medication was given and to which animals, there was also a specific record of the medications each animal (both sows and fattening pigs) had received.

If the withdrawal times have been observed, no drug-use documentation (generated either by the producer or the attending veterinarian) routinely accompanies the animals to slaughter. If the NFA personnel wish to know specific information from a farmer, the farmer is required to provide it. The farmers supplying pigs to all export slaughter facilities sign an agreement with the management of the slaughterhouses attesting that they will observe the required withdrawal times.

Animals for slaughter were marked with a permanent tattoo unique to this farm. Each farm has a unique registration number: this is the number tattooed when slaughter time is at hand. Finland is in the process of developing a nationwide animal identification system.

The following were stored in a small refrigerator in a room adjacent to the stalls: vaccines (inactivated erysipelas and parvovirus), antibiotics (oxytetracycline and procaine benzylpenicillin) and oxytocin. A practicing veterinarian initiated any necessary medication and provided instructions to the farmer and/or his wife to continue the medication as necessary.

The practicing veterinarian (he was present on the day of the farm visit) maintains his own records of all medications administered to the animals and dispensed to the farmer. A random selection of these records is reviewed by regional NFA veterinarians; an example of such a review was demonstrated in the field.

No concerns arose as a result of the farm visit.

## SLAUGHTER/PROCESSING CONTROLS

The Finnish inspection system had controls in place to ensure adequate humane handling and slaughter, boneless meat reinspection, identification of ingredients, control of restricted ingredients, formulations, packaging materials, laboratory confirmation, label approvals, inspector monitoring, processing equipment and records, post-processing handling, processing defect actions, and inspectors' processing control.

- ◆ In Est. 74, numerous instances of inadequate pre-boning trim (specks of rail dust and grease) were found by the provincial veterinarian who was leading the audit. He ordered the day's production to be re-inspected.

## HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B). Several deficiencies were identified:

- ◆ In Est. 18, there was a CCP for plastic-bagging the bung but not for evisceration. This was corrected immediately. Also, the plan had been verified, but the documentation of the verification needed improvement.
- ◆ A pre-shipment document review form had been developed in Est. 22, but it had not yet been implemented during production. Its use was initiated on the day of the audit.
- ◆ The management of Est. 62 had developed an “own control” program that approximated the HACCP requirements. There were action plans for each of the two hazards identified, but they were not called HACCP plans, and the hazards were not termed “CCPs.” The NFA officials ordered the establishment management to modify the program into a HACCP program *per se*, and the plant manager agreed to do so within two weeks of the audit; in the meantime, until all HACCP requirements were met, NFA ordered that no products from this establishment would enter the U.S.-eligible export chain. This was done satisfactorily as per the agreement.
- ◆ No formal HACCP system had been developed in Est. 74. The only “critical control point” that had been identified for the slaughter process was the application of the plastic bag around the bung by the first skinning operator; no frequency of monitoring was specified, and the only person designated to monitor the critical limit (zero-tolerance for fecal contamination) was the next operator, who was physically unable to see the critical area. Consequently, no documentation of the monitoring of the critical limit was attempted, or even possible, by the second operator. There was no documentation that the “own-check” plan had been validated using multiple monitoring results, and no written procedures to verify that the plan was being effectively implemented and functioning as intended.
- ◆ In Est. 78, documentation of preventive measures taken when critical limits were exceeded was inadequate.

## Testing for Generic *E. coli*

Six of the establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and were audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

According to information supplied to FSIS by Finland, Finland had adopted the FSIS regulatory requirements for generic *E. coli* testing with the exception of the following different equivalent requirements:

## 1. SAMPLING FREQUENCY

Finland had an equivalent alternative sampling frequency that was part of validated HACCP plans and that met the following equivalence requirements:

- The testing frequency must be based on production volume with a minimum of one test/week.
- The predominant class of animals slaughtered in an establishment must be sampled.

## 2. SAMPLE COLLECTOR: Government takes samples.

- There is a clearly written sampling plan with instruction for sample collection and processing that will be universally followed.
- The government has a means of ensuring that sample collection activities are appropriate.
- The government uses the test results to verify establishment slaughter, processing and dressing controls for fecal contamination.

The on-site audits of the actual generic *E. coli* testing programs in practice in the establishments, however, resulted in the following observations, which were found to be at variance with the basic FSIS regulatory requirements:

- ◆ None of the slaughter establishments except Est. 22 had conducted a baseline study, as required, to determine the “normal” levels of generic *E. coli*, nor had any of these establishments developed a statistical process control procedure for evaluating the results of the *E. coli* testing.
- ◆ In Establishments 10, 18, and 22 the establishment laboratory technicians were taking the generic *E. coli* samples, under the supervision of the Veterinarians-In-Charge. In Est. 74, the IIC and the laboratory technician were taking the samples together. The Finnish officials had not informed FSIS that they had changed the sampling procedure as required.
- ◆ Instead of the FSIS method for culturing field samples, the laboratories were using the Nordic Committee for Food Analysis (NMKL) 147:1993 method. The Finnish officials had not informed FSIS that they had changed the sampling procedure as required.

All establishments had adequate controls in place to prevent meat products intended for Finnish domestic consumption from being commingled with products eligible for export to the United States.

## ENFORCEMENT CONTROLS

### Inspection System Controls

Except as noted below, and with the exception of the two unacceptable establishments (Ests. 74 and 78), the NFA inspection system controls were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. These included control of restricted product and inspection samples, boneless meat reinspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, and inspection supervision and documentation. The only live animals imported into Finland were for breeding purposes. No meat was imported from other countries for use in U.S.-eligible products. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

- ◆ The Auditor also determined that only one inspection official in a position of authority in the field had had formal HACCP training. The vast majority of the NFA personnel stationed in establishments certified as eligible to export to the United States were not adequately educated regarding their responsibilities in monitoring the establishments' compliance with the HACCP requirements.

### Testing for *Salmonella* Species

Six of the establishments were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

According to the information provided to FSIS by the Finnish meat inspection officials, Finland had adopted the FSIS regulatory requirements for HACCP. *Salmonella* testing was reported to be the same as in the U.S., with exception of the following equivalent measures:

1. SAMPLE COLLECTOR: Establishments take samples.
  - The government of Finland provides a clearly written sampling plan with instructions for sample collection and processing that is followed by all applicable export establishments.
  - All applicable veterinarians are properly and uniformly trained. The veterinarians train the establishment employees. The government of Finland ensures that establishment sample collection activities are appropriate. The veterinarian oversees and monitors the sampling on a random basis. The veterinarian is in the establishment whenever a sample is being collected and is notified of the sample prior to it being collected. The procedures of the sample collector are also ensured by unannounced supervisory/compliance audits conducted by a Provincial Veterinarian and an inspector of the EELA.

- The government of Finland uses the test results to monitor establishment performance over time.
- The government of Finland takes immediate action any time an establishment fails to meet a *Salmonella* performance standard.

## 2. LABORATORIES: Private laboratories analyze samples.

- The laboratories are independent non-government or establishment laboratories that are accredited by the government of Finland and must comply with ISO 25 or EN 450001 standards. The laboratories are required to participate in inter-calibration tests to ensure laboratory analyses are properly performed.
- All accredited laboratories have a formal program that ensures lab personnel are properly trained. There are suitable facilities and equipment, a written quality assurance program, and there are adequate reporting and record keeping facilities.
- Test results are reported directly to inspection personnel.

## 3. SALMONELLA TESTING STRATEGY.

- Finland uses a continuous, ongoing sampling program to determine when to initiate additional *Salmonella* testing. All U.S. export establishments are included in the sample pool. The Finnish Performance Standards and enforcement procedures are stricter than FSIS requirements and are applied uniformly to all applicable export establishments. The sampling program is based on each establishment's production, with a minimum of one sample per production day (large establishments) or one sample per week (small establishments). If one positive is found during the ongoing program, Finland requires the establishment to take corrective action and immediately initiates a second sample set.
- The second sample set consists of 59 samples taken during the first 5 consecutive workdays (after confirmation of the positive), and continues at a rate of one sample per day for an additional 50 days of production (for swine). If two positives are found during the second sample set, the establishment is removed from the list of approved export establishments.
- Finland uses a continuous, ongoing sampling program to determine when to initiate additional *Salmonella* testing. All products for which there is a U.S. performance standard are included in the sample pool.
- Finland's testing program has statistical criteria for evaluating test results.
- The percentage of *Salmonella* positives over time meets the FSIS percentage of positives in the FSIS standard.

#### 4. SAMPLING TOOLS.

- A swab-pad sampling tool is used. The swab-pad tool is an internationally recognized sample collection tool for sampling *Salmonella* on meat or poultry products.
- The swab-pad is sensitive enough to gather *Salmonella* that are present at the sample sites.
- The sampling tool does not contaminate the surfaces of the carcass.

#### 5. SAMPLING TECHNIQUES: Time of collection of samples.

- Samples are taken at the end of the slaughter or production process.
- Samples are taken prior to the carcass being cut and/or packaged.

#### 6. SAMPLING TECHNIQUES: Compositing samples.

- Samples are composited at the laboratory rather than at the establishment.
- All of the sampling sites designated in the PR/HACCP final rule, or equivalent sampling sites, are included in the analysis.

#### 7. ANALYTICAL METHODS: Different methods.

- The laboratories use ISO 6579 to analyze for *Salmonella*. ISO 6579 is an internationally recognized method of analysis for detecting *Salmonella* and is closer to the FSIS method than the AOAC method.

#### 8. LOCATION AND SIZE OF SAMPLE SITES. Location of sample sites; Size of sample sites.

- Finland collects samples from two large sites. These two sites include the sample collection areas from all three FSIS sample sites.
- The sample sites encompass a large enough surface area to ensure that the effectiveness of the HACCP plans will be evaluated.
- The two sample sites provide the same probability of detecting the presence of *Salmonella* as the FSIS sample sites.

The auditor determined that Finland's officials had deviated in three important areas from the procedures that had been submitted to FSIS as standard procedures, and had not informed FSIS of their intent to make these changes for an equivalence determination prior to their implementation:

- Only two sample sites (brisket and rump) were being used for beef. FSIS requires the inclusion of a sampling site on the shank as well, as per the criteria stated above. (The jowl area was also sampled in swine, as required.)
- In-plant inspection officials were taking the *Salmonella* samples. The Finnish officials had not informed FSIS that they had changed the sampling procedure as required.
- Instead of the ISO 6579 method, the laboratories were using the Nordic Committee for Food Analysis (NMKL) 71:1992, [modified by] EELA 3432: 999 method. The Finnish officials had not informed FSIS that they had changed the sampling procedure as required.

### Species Verification

- ◆ At the time of this audit, Finland was not exempt from the species verification requirement; however, there was no species verification program in effect. There had been some confusion regarding the requirement, and the Auditor explained the requirement during the exit meeting.

### Monthly Reviews

Title 9 of the U.S. Code of Federal Regulations requires supervisory visits by a representative of the foreign inspection system, not less frequent than one such visit per month to each establishment certified, during periods when the establishment is engaged in producing products for exportation to the United States.

Finland had been divided into 5 regions. Each had Regional Veterinarians (there were a total of 16 at the time of this audit); they were all full-time employees of the Ministry of Internal Affairs. These were the officials who conducted the supervisory visits to establishments certified by Finland as eligible to export meat products to the United States. They were also responsible for animal welfare, disease control, and vaccinations. Their reports of reviews of the U.S.-eligible establishments were sent directly to Dr. Osmo Mäki-Petäys in the Meat and Fish Hygiene Unit.

All Regional Veterinarians must go through a special training period of courses in meat inspection veterinarians (a summary of this training had been provided and was attached to the 1999 country report) following the conclusion of their veterinary education and must pass an examination relating to meat inspection issues. Meat inspection is included in the veterinary curriculum (a strong emphasis is placed meat hygiene during the last of the 6 years).

The internal review program was applied only to export plants. The visits were usually announced in advance to the IIC, and enough notice was usually given to the establishment that a management representative would be present for the review. Unannounced visits were employed in the event of a suspected problem. The internal reviews were usually conducted

by a single auditor, with a target frequency of at least once during each month when an establishment produces any product that is eligible for export to the U.S. Records of audited plants were kept both centrally (at NFA headquarters) and in the establishments, and were maintained on file for at least five years.

The internal reviewers had an advisory function. They reported their findings to Dr. Osmo Mäki-Petäys, who then decided what actions were to be taken. Routine reports were sent by mail and could take from one week to two months to be reported to Dr. Mäki-Petäys. In the event of noncompliance, results were conveyed by telephone.

In the event that an establishment is determined to fail to meet U.S. requirements during a routine internal audit, all other U.S.-eligible establishments and cold stores are immediately informed, and International Policy Division in Washington, D.C. is also immediately notified. If the establishment management wishes to regain eligibility for access to the U.S. market, the management contacts EELA and requests another internal review.

- ◆ Only one of the Regional Veterinarians who participated in this new audit of Finland had had formal HACCP training. The rest of the NFA inspection personnel in the field, with whom the Auditor met and worked, were not adequately informed or educated regarding either (1) the establishments' responsibilities in fulfilling the requirements of a compliant HACCP program or (2) the responsibilities of the inspection personnel assigned to the individual establishments in monitoring, verifying, and documenting that the establishments' responsibilities were being met.

During the country entrance meeting, the officials stated that the Regional Veterinarians were kept informed of current U.S. requirements through semiannual training sessions, mail, and e-mail. With the exception of HACCP training, the internal reviewers were well informed and thorough in their roles as leaders of the individual establishment audits.

- ◆ In three establishments, the audit of the internal reviewers' reports revealed that the supervisory visits had not been conducted during some months: there had been no internal reviews in Est. 22 during July 2001, or in Est. 62 during November or December 2000 or February, March, May, or July 2001. Only three internal reviews had been conducted in Est. 6472 since the last FSIS audit of Finland in September-October 2000.

### Enforcement Activities

The Auditor advised the NFA officials of the FSIS website in general, and advised them of the availability of the Enforcement Quarterly in particular. The Finnish officials responded that, in the Finnish system, there was no equivalent material that was made available to the general public, but that enforcement actions, as well as all official reports made from reviews of establishments are available to the public through the equivalent of a Freedom-of-Information Act.

The auditor informed the Finnish meat inspection officials that a major emphasis would be placed upon enforcement controls, their documentation, and the availability of that documentation to FSIS auditors, during the routine audits to be conducted in Fiscal year 2002.

### Exit Meetings

An exit meeting was conducted in Helsinki on August 30. The Finnish participants were Drs. Anna-Maija Grönlund, Marjorikka Keränen, Eero Läikkö, Eija Läikkö, Anne Fagerlund, Leena Räsänen, and Marjatta Tahkio, Senior Veterinary Officers; Aldo Rizzo, Senior Researcher, EELA; and Matti Amo, Food & Health, Ministry of Agriculture, Food, and Fisheries. Also in attendance were Mr. Björn Engström, Agricultural Marketing Assistant, FAS, American Embassy, Stockholm and Dr. Gary D. Bolstad, International Audit Staff Officer, Field Operations, Food Safety and Inspection Service, U.S. Department of Agriculture. The following topics were discussed:

1. The findings in the seven establishments, as detailed in the body of this report, were discussed in detail. These included personal hygiene deficiencies, insanitary dressing procedures, failure to sterilize equipment as required, common contact, and inadequacies regarding condensation control, pre-boning trim, light at inspection surfaces, and maintenance of over-product structures and equipment. The NFA officials gave assurances that, in Establishments 10, 18, 22, 62, and 6472, all the deficiencies would be promptly corrected. They gave further assurances that, if/when the management of Ests. 74 and 78 should wish to have the establishments reinstated for U.S.-export eligibility, all the deficiencies identified would be addressed and corrected. The Auditor reminded the NFA officials that, before either of these establishments would be eligible for reinstatement, FSIS would have to be (1) notified in advance, (2) provided with documentation of the corrective actions, and (3) provided with the opportunity to visit the establishment(s) on-site to verify that they were back in compliance.
2. The Auditor explained in detail the specific deficiencies found with regard to the development and implementation of HACCP programs in the establishments and with NFA's monitoring of these programs. The NFA officials gave assurances that they would see to it that the field inspection officials with positions of responsibility for establishments certified to produce products for U.S. eligibility would receive the necessary formal HACCP education as soon as possible, and that they would promptly develop and implement programs for these field personnel to monitor, evaluate, and document establishment compliance with the HACCP requirements. The Auditor also provided the NFA officials with an example of how the results of a baseline study for generic *E. coli* sampling could be used to develop a statistical process control system for evaluating those results.
3. The Auditor stressed the FSIS requirement that, until any proposed changes to sampling and testing programs for generic *E. coli* and *Salmonella* species have been submitted to FSIS for equivalence determination, the programs must be continued as stated in the

documents previously submitted to FSIS and determined to meet equivalence criteria. Finland had modified sampling procedures and culturing methodologies without informing FSIS. The auditor advised them that, until the Equivalence Branch determines that the new procedures are equivalent, the procedures in place must continue to be employed. The NFA officials stated that they understood the requirement and would ensure that it would be met.

4. At the time of this audit, Finland had not applied to FSIS for an exemption from the species verification requirement; however, there was no species verification program in effect. There had been some confusion regarding the requirement, and the Auditor explained that, unless a country is granted an exemption from this requirement, the country must have a species verification program in place, and advised the NFA officials of the importance of developing and implementing such a program as soon as possible. The NFA officials stated that they understood the requirement.
5. The Auditor advised the NFA officials that, when the internal reviewers find that problems that have been identified are not being adequately addressed, more decisive actions should be taken, including suspending U.S. eligibility of, or delisting, those plants that really do fail to meet basic U.S. requirements.
6. The Auditor stressed the importance of the monthly supervisory visits during periods when an establishment is engaged in producing products for exportation to the United States. The NFA officials agreed to correct this immediately.

## CONCLUSION

A number of serious deficiencies were identified during the course of this audit, calling into question whether the inspection system of Finland was providing adequate controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments:

- ◆ Serious sanitation deficiencies were found in three of the seven establishments.
- ◆ There were inadequacies in the development and implementation of HACCP programs. Furthermore, field inspection personnel had not been adequately educated regarding HACCP requirements. This was a repeat finding.
- ◆ In five of the six slaughter establishments, statistical control procedures had not been developed to evaluate generic *E. coli* testing results. This was a repeat finding.
- ◆ No species verification was being performed in any of the establishments.
- ◆ Finland had modified sampling procedures and culturing methodologies without informing FSIS.
- ◆ Supervisory visits by internal reviewers had not been conducted monthly in three plants.

Seven establishments were audited: four were acceptable, one was evaluated as acceptable/re-review, and two were unacceptable. The deficiencies encountered during the on-site establishment audits, in those establishments which were found to be acceptable, were adequately addressed to the auditor's satisfaction.

Dr. Gary D. Bolstad  
International Audit Staff Officer

(Signed) Dr. Gary D. Bolstad

### **ATTACHMENTS**

- A. Data collection instrument for SSOPs
- B. Data collection instrument for HACCP programs
- C. Data collection instrument for *E. coli* testing
- D. Data collection instrument for *Salmonella* testing
- E. Laboratory Audit Forms
- F. Individual Foreign Establishment Audit Forms
- G. Written Foreign Country's Response to the Draft Final Audit Report

### Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1. Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Frequency addressed	6. Responsible indiv. identified	7. Documentation done daily	8. Dated and signed
10	√	√	√	√	√	√	√	√
18	√	√	√	√	√	√	*	√
22	√	√	√	√	√	√	√	√
62	√	√	√	√	√	√	√	√
78	√	√	√	√	√	√	Inadeq.	√
74	*	√	Inadeq.	√	√	√	No	√
6472	√	√	√	N/A	√	√	√	√

\*18 There was some documentation of operational sanitation activities, but it was in need of improvement.

\*74 Bits and pieces of pre-operational sanitation documentation were available, but very little was available regarding operational sanitation. There was no concise description of the sanitation program, and the only daily documentation of operational sanitation activities was the monitoring of sterilizer temperatures.

78 Documentation of operational sanitation activities was inadequate (this was a repeat finding). There was no documentation of condensation control (condensation was one of the major findings during the audit).

## Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. (except Est. 6472, which was a cold-storage facility) was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment has conducted a hazard analysis that includes food safety hazards likely to occur.
3. The analysis includes the intended use of or the consumers of the finished product(s).
4. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
5. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
6. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
7. The plan describes corrective actions taken when a critical limit is exceeded.
8. The HACCP plan was validated using multiple monitoring results.
9. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
10. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
11. The HACCP plan is dated and signed by a responsible establishment official.
12. The establishment is performing routine pre-shipment document reviews.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis conducted	3. Use & users included	4. Plan for each hazard	5. CCPs for all hazards	6. Monitoring is specified	7. Corr. Actions are described	8. Plan validated	9. Adequate verific. Procedures	10. Adequate documentation	11. Dated and signed	12. Pre-shipment doc. review
10	√	√	√	√	√	√	√	√	√	√	√	√
18	√	√	√	√	*	√	√	√	*	√	√	√
22	√	√	√	√	√	√	√	√	√	√	√	*
62	√	√	√	*	*	√	√	√	√	√	√	No
74	√	√	√	Inad.	Inad.	Inad.	√	Inad.	No	No	√	N/A
78	√	√	√	√	√	√	√	√	√	Inad.	√	√
6472	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

\*18 There was a CCP for plastic-bagging the bung but not for evisceration. This was corrected immediately. The plan was verified, but the documentation of the verification needed improvement. The HACCP-trained establishment employee had recently left the establishment's employment; the management was seeking a replacement.

\*22 A pre-shipment document review form had been developed but had not yet been implemented during production. Its use was initiated on the day of the audit.

\*62 This establishment had developed an "own control" program that approximated the HACCP requirements. There were action plans for each of the two hazards identified, but they were not called HACCP plans, and the hazards were not termed "CCPs." The NFA officials ordered the establishment management to modify the program into a HACCP program *per se*, and the plant manager agreed to do so within two weeks of this audit; in the meantime, until all HACCP requirements were met, NFA ordered that no products from this establishment would enter the U.S.-eligible export chain. This was done.

*NOTE: Both NFA and establishment management officials stated that the previous FSIS auditor had informed them that it was not necessary to designate the hazards as CCPs, the tolerances as Critical Limits, or the action plans as HACCP plans.*

\*74 (Only) the establishment manager had attended a "HACCP" course, some six years ago. The "own control" system in this est. was designed by the parent company. The previous FSIS auditor had briefly audited some of the documentation and

the “HACCP” system had been “developed” during his audit. Neither the establishment management nor the NFA officials either assigned to or in a supervisory position to review the establishment had understood the HACCP requirements.

78 Documentation of corrective actions when critical limits were exceeded was inadequate.

### Data Collection Instrument for Generic *E. coli* Testing

Each establishment (except Est. 6472, which was a cold-storage facility) was evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written procedure for testing for generic *E. coli*.
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is/are being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. #	1. Written procedure	2. Sampler designated	3. Sampling location given	4. Predominant species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
10	√	√	√	√	√	√	√	√	√	√
18	√	√	√	√	√	√	√	√	√	√
22	√	√	√	√	√	√	√	√	√	√
62	√	√	√	√	√	√	√	no	√	√
74	√	√	√	√	√	√	√	√	√	√
78	√	√	√	√	√	√	√	√	√	√
6472	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

### Data Collection Instrument for *Salmonella* testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. *Salmonella* testing is being done in this establishment.
2. Carcasses are being sampled.
3. Ground product is being sampled.
4. The samples are being taken randomly.
5. The proper carcass site(s) and/or collection of proper product (carcass or ground) is being used for sampling.
6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. #	1. Testing as required	2. Carcasses are sampled	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
10	√	√	N/A	√	√	N/A
18	√	√	N/A	√	√	N/A
22	√	√	N/A	√	√	N/A
62	√*	√	√	√	√	N/A
74	√	√	N/A	√	*	N/A
78	√	√	N/A	√	*	N/A
6472	N/A	N/A	N/A	N/A	N/A	N/A

74, 78 Only two sample sites (brisket and rump) were being used swabbed. FSIS requires that a shank site is also swabbed.